K03 2877/S1

MAY - 7 2004

X. PREMARKET NOTIFICATION SUMMARY

Submitted by:	Vitrolife Sweden AB Faktorvägen 13 SE-434 37 Kungsbacka SWEDEN
Contact Person:	Ms. Nina Arvidsson Vitrolife Sweden AB Faktorvägen 13 SE-434 37 Kungsbacka SWEDEN Mr. Gary L. Yingling Kirkpatrick & Lockhart, LLP 1800 Massachusetts Avenue, NW Washington, DC 20036-1800
Date Prepared:	September 10, 2003
Trade Name:	G-OOCYTE™
Common Name:	Assisted Reproduction Media
Classification Name:	Reproductive Media and Supplements (21 C.F.R. § 884.6180)
Predicate Device:	G-MOPS™ (K021893)
Description of the Device:	MOPS buffered medium. For use after the addition of G-MM™ or HSA-solution™ and temperature equilibration at +37°C and ambient atmosphere.
Intended Use:	Medium for *In Vitro* Fertilization Procedures
Indications for Use:	For the support of the oocyte during intracytoplasmic sperm injection.
Technological Characteristics:	The technological characteristics of G-OOCYTE are essentially similar to those of the predicate device. Formulation changes were made with the needs of the denuded unfertilized oocyte in mind. None of these changes raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2004

Vitrolife Sweden AB
% Gary L. Yingling, Esq.
Consultant
Kirkpatrick & Lockhart, L.L.P.
1800 Massachusetts Avenue, NW
WASHINGTON DC 20036-1800

Re: K032877
Trade/Device Name: G-OOCYTE™ - Assisted Reproductive Media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: February 19, 2004
Received: February 23, 2004

Dear Mr. Yingling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032877

Device Name: G-OOCYTE™
Assisted Reproduction Media

Indications For Use: For the support of the oocyte during intracytoplasmic sperm injection

Prescription Use __x____ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032877